K071496

AUG 15 2007

510(k) Summary

Colorado Catheter Company iCath™ and SterileSure™ Urinary Catheterization Devices

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: _____

Contact Person: Andy Black
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400 North Rand Rd.
North Barrington, IL 60010

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Date Prepared: May 8, 2007

Device Name and Classification

Classification Name:	Urological Catheter and Accessories
Common /Usual Name:	Urinary Catheter
Proprietary Name:	iCath™, SterileSure™
Device Classification:	Class II
Regulation Number:	21 CFR Ref. § 876.5130
Product Code:	EZD

Manufacturer

PyMPSA
3609 Juan de la Barrera St, Alamo Industrial
Guadalajara, Jalisco, Mexico C.P. 44590

Device Description

The iCath™ and SterileSure™ are intended to be disposable medical devices that offer a pre-lubricated self catheterization alternative that does not require the application of lubricant prior to use to facilitate the insertion of a urinary catheter. Although nearly identical, the iCath™ is designed and intended for outpatient use, and the SterileSure™ is designed and intended for inpatient use administered to a patient under the care of medical personnel.

The iCath™ and SterileSure™ are intended to be used to drain urine from the bladder. The devices are provided sterile and for single-use only. Both consist of a catheter assembled within a thin, flexible sheath to minimize patient contact and reduce contamination. The sheath is connected to an introducer tip that is inserted into the urethra to facilitate advancement of the catheter into the urethra.
The introducer tip of the iCath™ contains a lubricant reservoir feature in which the catheter is lubricated prior to insertion with a water-soluble hydrophilic water-based lubricant. The SterileSure™ is prelubricated with the water-soluble hydrophilic water-based lubricant.

The devices are packaged singly with a urine drainage bag, or in a kit with accessories including benzalkonium chloride swabsticks or provodine iodine swabsticks, gauze pad, and urine collection container or urine drainage bag, and non-latex, powder-free gloves

Substantial Equivalence Claim

Colorado Catheter Company believes the proposed iCath™ and SterileSure™ is substantially equivalent in form and function to Mentor Self-Cath® HydroGel™ Intermittent Urethral Urinary Catheter, which was cleared under 510(k) number K052440.

Indications for Use

The Colorado Catheter iCath™ and SterileSure™ are intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Summary of Testing

Cytotoxicity (Agar Diffusion – ISO Method): The introducer tip of the iCath™ and SterileSure™ induced mild reactivity with a Grade of 2. The catheter portion of the device is pre-approved by the FDA (510k number K871999) for the intended use. Therefore the test devices meet the requirements of this test.

Guinea Pig Maximization (Two extracts): There were no signs of sensitization with the test article; the test article is not considered to elicit contact dermal allergenicity.

Systemic Toxicity (Acute Systemic Injection with Saline and Vegetable Oil Extracts: The test article met the requirements of the systemic injection test.

Acute Vaginal Irritation: The test article meets the requirements of the vaginal irritation test.

Performance Testing: The iCath™ and SterileSure™ met all performance requirements for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Colorado Catheter Company, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K071496
Trade/Device Name: Colorado Catheter iCath and SterileSure
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Codes: NWO and EZD
Dated: July 13, 2007
Received: July 16, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Benzalkonium Chloride and Povidone-Iodine, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division

of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Divices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071496
Device Name: Colorado Catheter iCath and Colorado Catheter SterileSure

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071496